UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *EX REL.* TERESA ROSS,

Plaintiff/Relator,

v.

GROUP HEALTH COOPERATIVE, INDEPENDENT HEALTH CORPORATION, DxID LLC, DR. JOHN HAUGHTON, and BETSY GAFFNEY

Defendant.

Case No. 12-CV-00299-WMS

MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS FIRST AMENDED COMPLAINT AGAINST DEFENDANT GROUP HEALTH COOPERATIVE

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Relator Teresa Ross ("Relator") initiated this *qui tam* action in 2012 under the Federal False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq*., against Group Health Cooperative ("GHC"), Independent Health Corporation ("IHC"), Independent Health Association ("IHA"), DxID LLC ("DxID"), and Dr. John Haughton and Betsy Gaffney of DxID (collectively, "Defendants"). Defendant GHC respectfully submits this Memorandum of Law in support of its Motion to Dismiss Relator's First Amended Complaint ("FAC") for failure to state a claim under Federal Rule of Civil Procedure ("Rule") 12(b)(6), failure to plead fraud with particularity under Rule 9(b), and failure to meet Rule 8(a)'s plausibility requirements.

I. INTRODUCTION

The FCA demands that relators satisfy a rigorous pleading standard—and for good reason: a relator's perspective is all too easily colored by subjective experience, bias or self-interest. This case presents a textbook example of these issues. Throughout Relator's FAC, she offers only conclusions, generalizations, and personal interpretations. Indeed, Relator's entire FAC boils down to a non-actionable difference of opinion between her allegedly "conservative" method for evaluating the underlying documentation for certain medical conditions and her perception of an "aggressive" approach taken by Defendants. Not surprisingly, Relator offers no statutory or regulatory authority to support her allegations that Defendants' actions resulted in false claims, much less that Defendants, and especially GHC, ever acted in a knowingly false or fraudulent manner. The FCA demands more than a dispute over judgment calls. Relator's FAC does not—and cannot—show how GHC's alleged acceptance of interpretations with which Relator disagrees resulted in specific false diagnoses being coded and submitted to the Centers for Medicare and Medicaid Services ("CMS"). The Court should therefore dismiss her FAC with prejudice.

II. STATEMENT OF FACTS

GHC was founded in 1947 as a nonprofit, consumer-governed health organization. FAC ¶ 17. Based in Seattle, Washington, GHC "catered to the public interest" by supporting low-income patients and delivering affordable, quality healthcare—through its own facilities and through a network of healthcare providers—thereby consistently earning "high marks." FAC ¶¶ 17, 73.[1] Relator's allegations relate to certain aspects of GHC's business for two years (2010 and 2011) under the Medicare Advantage ("MA") program.

A. Medicare Advantage

In the MA program, private companies like GHC—referred to as Medicare Advantage Organizations ("MAOs")—administer Medicare benefits under contracts with CMS. MAOs provide those benefits to their population of beneficiaries through arrangements with various types of healthcare providers. MAOs in turn receive *prospective* monthly payments from CMS reflecting the *expected* costs of providing care to their beneficiaries. 42 U.S.C. § 1395w-23(a). This program differs structurally from original Medicare (Medicare Parts A and B); there, healthcare providers generally bill CMS directly *after* a patient encounter for services specifically performed (often called fee-for-service billing). *See* 42 U.S.C. § 1395w-21(a); 42 U.S.C. §1395c *et seq*.; 42 U.S.C. §1395j *et seq*.

Congress has made clear that a statutory goal of tying MAO payments to the *expected* costs of treating beneficiaries (rather than on a fee-for-service basis) is to cover the financial risks MAOs assume to provide care for their enrolled beneficiaries. *See* 42 U.S.C. § 1395w-23(a)(1)(C)(i). To accomplish this, Congress enacted a reimbursement system known as risk

[1] In 2017 (well after the allegations in the FAC), GHC was acquired by Kaiser Permanente and is now known as Kaiser Foundation Health Plan of Washington.

adjustment, which adjusts payments to MAOs according to their beneficiaries' demographic information and health status. *See id*. This "allows CMS to pay plans for the risk" of their beneficiaries and to "make appropriate and accurate payments for enrollees with differences in expected costs." CMS, *Medicare Managed Care Manual*, ch. 7, § 20.[2]

CMS bases "health status" adjustments on beneficiary diagnosis information submitted by MAOs for each calendar year. MAOs are responsible for receiving this diagnosis information from providers and transmitting it to CMS, generally within 13 months of the completion of the calendar year. 42 C.F.R. § 422.310. MAOs' diagnosis submissions to CMS do not contain requests for payment and are not claims. *See* CMS, *2013 National Technical Assistance Risk Adjustment 101 Participant Guide*, § 4.3.[3] CMS then uses its own CMS Hierarchical Condition Category ("HCC") and RxHCC models to group diagnosis codes together. The CMS HCC model groups diagnoses in a way that accounts for the clinical characteristics, relative severity, and cost implications of the reported diagnoses. *Medicare Managed Care Manual*, ch. 7, § 70.1. CMS's HCC model "[u]ses diagnostic information from a base year to predict Medicare benefit costs for the following year." *Id.* at § 70, Table 2. CMS includes conditions in the model if the conditions are statistically predictive of *overall* increases in health care costs in the subsequent year (the payment year)—not because the presence of a condition in the base year means *that particular condition* will persist in the payment year or, if it does, will cause the MAO to incur costs. *See id.* at § 70.1. CMS therefore uses HCCs to calculate future overall payments to the MAO for each beneficiary irrespective of what costs actually are incurred in the future and for

[2] *Available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c07.pdf.
[3] *Available at* https://www.csscoperations.com/Internet/Cssc3.Nsf/files/2013_RA101ParticipantGuide_5CR_081513.pdf/$File/2013_RA101ParticipantGuide_5CR_081513.pdf.

what conditions. In doing so, CMS applies the relevant HCC to each beneficiary's payment calculation once for the relevant year, regardless of how many diagnosis codes relating to that HCC are submitted to CMS. *See* CMS, *2008 Risk Adjustment Data Technical Assistance for Medicare Advantage Organizations Participant Guide* ("Participant Guide"), § 1.3.[4]

B. Relator's Allegations

Relator worked at GHC for over fourteen years in multiple positions. FAC ¶ 18. Relator acknowledges that during this time "GHC ha[d] several mechanisms to ensure proper coding and documentation" for diagnosis information submitted to CMS for risk adjustment purposes, including medical record reviews conducted by the Insurance and Health Data Analysis department and a "software algorithm that mines its claims data to . . . flag potential problems." FAC ¶ 76; *see also* ¶¶ 74–78. Based on these efforts, GHC would submit diagnosis data corrections to CMS as appropriate. FAC ¶ 78.

Relator alleges that GHC hired DxID in November 2011 "to conduct a retrospective review of [GHC's] risk adjustment claims" for encounters with patients from 2010. FAC ¶¶ 87–88. Although she concedes that retrospective reviews of this type can result in new "legitimate" diagnosis codes for submission to CMS, *see e.g.*, FAC ¶ 84, she alleges that GHC's engagement with DxID resulted in false submissions to CMS. FAC ¶¶ 91–95.

While Relator was not a coder or provider and offers no basis to validate her personal understanding of MA documentation or coding requirements, her allegations that DxID's engagement resulted in false submissions to CMS appear to be based on her opinion that the documentation DxID reviewed contained insufficient support for the resulting diagnosis codes

[4] *Available at* https://www.csscoperations.com/Internet/Cssc3.Nsf/files/participant-guide-publish_052909.pdf/$File/participant-guide-publish_052909.pdf.

and did not adhere to her own "conservative" approach to coding. FAC ¶ 81; *see also* ¶¶ 97, 99–105, 117. Relator provides two alleged bases for this view.

First, she alleges that "DxID proposed using invalid documentation sources"—problem lists and indications that a patient "had a diagnosis," without an indication of treatment—generally stating that such sources are in violation of "CMS Rules." FAC ¶ 97. The Participant Guide on which she generally relies in her FAC, however, provides both "guidance for problem lists" and instructs generally that all conditions that "require or affect patient care treatment *or* management" should be coded. Participant Guide, §§ 7.2.4, 6.4.1 (emphasis added).

Relator alleges that she—along with a "physician partner," Dr. Don Rappe—reviewed 200 of 4,578 diagnosis codes submitted to CMS as a result of DxID's review for 2010 dates of service, concluding that 74% of the 200 codes "did not have sufficient documentation to justify submitting the diagnosis." FAC ¶¶ 112, 120, 121, 124, 125. Relator alleges that GHC disagreed with the majority of Relator's conclusions, but authorized her to send 40 of the codes to DxID for re-review and discussion. FAC ¶ 126. Relator ultimately agreed with DxID's explanations for 15 of the codes but concluded that the remaining 25 were not supported "[e]ven under the most generous *interpretation* of CMS rules." FAC ¶ 128 (emphasis added). Relator elsewhere concedes that DxID submitted data corrections to CMS for diagnosis codes that "it had added, and later determined to be unsupported through a quality control process." FAC ¶ 122.

Second, Relator alleges that "DxID asked GHC's leadership to approve or reject certain coding policies . . . that were largely in violation of CMS rules." FAC ¶ 99. She similarly does not specify which "CMS rules" she claims were not followed, but merely refers to the coding policies as "flawed," "bogus," and "very aggressive." *E.g.*, FAC ¶¶ 104, 106, 107, 110.

Although Relator's allegations focus primarily on medical encounters occurring in 2010,

Relator also alleges "[u]pon information and belief" that "DxID's review process for 2011 likely generated more unsubstantiated codes than the previous review because DxID had more time to conduct its review." FAC ¶ 138.

C. Procedural History

Relator filed her complaint, under seal, on April 11, 2012. Docket No. 1. On February 5, 2016, she filed her FAC. Docket No. 32. Relator alleges that DxID and GHC "conspired to submit and did submit to CMS" risk adjustment data that she believes to be false based on her review and applying her layperson's understanding of the documentation standard she believes is required. FAC ¶¶ 148–49. Relator brings one cause of action against "Defendants," including GHC, under four sections of the FCA: 31 U.S.C. §§ 3729(a)(1)(A)–(C)), (G). FAC ¶¶ 160–67.

In June 2012, the United States filed its first of fifteen motions for extension of time to make its intervention decision. Docket No. 4, No. 59. On June 21, 2019, the United States filed a "Notice That It Is Not Intervening At This Time" in this matter, Docket No. 62, and the Court subsequently ordered a partial lifting of the seal on this case to allow for service of the FAC. Docket No. 63. The Court approved the parties' stipulation to extend the time for Defendants to answer or otherwise move with respect to the FAC until October 16, 2019. Docket No. 82.

III. LEGAL STANDARD

In a motion to dismiss for failure to state a claim under Rule 12(b)(6), a plaintiff's factual allegations are accepted as true, but "legal conclusions, and threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Harris v. Mills*, 572 F.3d 66, 72 (2d Cir. 2009) (quotation omitted); *see Nielsen v. Rabin*, 746 F.3d 58, 62 (2d Cir. 2014). Under Rule 8(a), a complaint "must contain sufficient factual matter, accepted as true, to state a claim for relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)

(quotation omitted). To determine whether a complaint is plausible, a court should similarly not assume the truth of legal conclusions, recitals of the elements of a cause of action, or threadbare assertions. *See id*.

Claims under the FCA are additionally subject to the heighted pleading requirements of Rule 9(b). Rule 9(b) serves an important gatekeeping function in FCA cases by requiring "a party [to] state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Rule 9(b) "is designed to provide a defendant with fair notice of a plaintiff's claim, to safeguard a defendant's reputation from improvident charges of wrongdoing, and to protect a defendant against the institution of a strike suit." *United States ex rel. Ladas v. Exelis, Inc.*, 824 F.3d 16, 25–26 (2d Cir. 2016) (quotation omitted).

A complaint brought under the FCA must allege several elements: (i) the existence of a "false or fraudulent claim for payment or approval," or "a false record or statement material to a false or fraudulent claim," or "an obligation to pay or transmit money or property to the Government" (i.e., a false claim); (ii) that any such claim was "material" to the government's decision to pay; and (iii) that any such claim was submitted "knowingly." 31 U.S.C. §§ 3729(a)(1)(A)–(B), (G). A relator must plead the existence of false claims and materiality (i.e., elements (i) and (ii) above) with particularity under Rule 9(b). *Universal Health Servs. v. United States ex rel. Escobar*, 136 S. Ct. 1989, 1994 (2016); *Ladas*, 824 F.3d at 25.

To meet the Rule 9(b) standard, the Second Circuit requires relators to: "(1) Specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Ladas*, 824 F.3d at 25; *see also United States ex rel. Grubea v. Rosicki, Rosicki & Assocs. P.C.*, 318 F. Supp. 3d 680, 696 (S.D.N.Y. 2018). In doing so, relators must plead "*specific identified*

false invoices submitted to the government" or "[make] plausible allegations creating a strong inference that specific false claims were submitted to the government *and* that the information that would permit further identification of those claims is peculiarly within the opposing party's knowledge." *United States ex rel. Chorches v. Am. Med. Response, Inc.*, 865 F.3d 71, 86 (2d Cir. 2017) (emphasis added). If a relator "*can* identify examples of actual claims[, a relator] *must* do so at the pleading stage." *Id*.

Similarly, "a misrepresentation about compliance with a statutory, regulatory, or contractual requirement *must be material* to the Government's payment decision in order to be actionable under the False Claims Act." *Escobar*, 136 S. Ct. at 2002 (emphasis added). "Materiality must be pleaded with particularity under Rule 9(b)." *See Grabcheski v. Am. Int'l Grp.*, 687 F. App'x 84, 87 (2d Cir. 2017). Under the FCA's "materiality requirement, statutory, regulatory, and contractual requirements *are not automatically material*, even if they are labeled conditions of payment." *Escobar*, 136 S. Ct. at 1994 (emphasis added). The "materiality standard is demanding" and materiality "cannot be found where noncompliance is minor or insubstantial." *Id.* at 2003.

A relator must also plead actual knowledge, deliberate ignorance or reckless disregard to meet the "knowledge" requirements of the FCA. 31 U.S.C. § 3729(b). While scienter "may be alleged generally," Fed. R. Civ. P. 9(b), the Second Circuit has "repeatedly required plaintiffs to plead the factual basis which gives rise to a strong inference of fraudulent intent." *United States ex rel. Tessler v. City of N.Y.*, 712 F. App'x 27, 29 (2d Cir. Oct. 5, 2017) (quotation omitted).

IV. ARGUMENT

For her claims under 31 U.S.C. §§ 3729(a)(1)(A) and (B), Relator fails to plead that GHC submitted any false claims that were material to CMS's decision to pay GHC. Her conspiracy

and "reverse" FCA claims under 31 U.S.C. §§ 3729(a)(1)(C) and (G) are even more deficient, as she fails to even allege the basic elements of these claims. And for all of her claims, Relator fails to allege the required factual basis that GHC acted "knowingly." For these reasons, Relator's FAC should be dismissed.

A. Relator's Generalized Allegations Against GHC Fail to Establish Particular False Claims or Materiality

Relator fails to allege (1) the submission of any false claims to CMS, and (2) that any such claims would be material to CMS's decision to pay with the particularity required by Rule 9(b). Nor could Relator remedy this with additional detail, as her allegations are premised on her interpretations of sub-regulatory guidance and her own views, including her personal application of what she views as a "conservative" coding method. FAC ¶ 81; *see also* FAC ¶¶ 97, 99–105, 117. Neither her interpretations of sub-regulatory guidance nor her personal subjective opinions suffice to plead an FCA claim.

1. Relator fails to allege that GHC submitted, or engaged in a scheme to submit, false claims to CMS under 31 U.S.C. §§ 3729(a)(1)(A) and (B).

Under the Second Circuit's requirements, because Relator does not allege that the information she needs is peculiarly within GHC's or any other Defendants' knowledge, she must plead "specific identified false invoices submitted to the government." *See Chorches*, 865 F.3d at 86. However, Relator has not done so, nor can she given that her allegations rely on her own subjective opinions and a misunderstanding of what constitutes a claim in Medicare Advantage.

a. Relator has not alleged that GHC submitted or caused to be submitted "claims" to CMS.

As an initial matter, Relator fails to identify an actionable "claim." Relator wrongly *assumes* that individual diagnosis codes submitted to CMS are "claims," but an individual diagnosis code submission to CMS in the MA program is not a "request or demand . . . for

money or property." 31 U.S.C. § 3729(b)(2)(A). As CMS explains in its technical assistance guidance, MA programs submit multiple diagnosis codes—potentially millions at a time—in batches via the Risk Adjustment Processing System (RAPS), and CMS then reviews the data and applies its risk adjustment system to calculate risk scores. CMS, *2013 National Technical Assistance Risk Adjustment 101 Participant Guide*, § 4.3 (explaining the data submission format, which does not include a request for payment). Given that these data submission batches lack a request for funds, the diagnosis codes contained within cannot constitute a false "claim" for FCA purposes. *See, e.g.*, *United States v. Krizek*, 111 F.3d 934, 939–40 (D.C. Cir. 1997) (holding that district court "incorrectly defined claim" under FCA when it concluded that "because the government used the [diagnosis] code in processing the claims, the [diagnosis] code . . . must be the claim"); *United States ex rel. Bahnsen v. Bos. Sci. Neuromodulation Corp.*, No.11-1210, 2018 WL 4604307, at *4 (D.N.J. Sept. 24, 2018) (holding that forms submitted to the government were "claims," "regardless of the number of diagnostic codes or line entries included on each form" and that the codes themselves were not claims). Relator points to no other "claims" in her FAC.

In any event, Relator also has not pleaded with *particularity* that GHC actually submitted or caused to be submitted to CMS *any* of the DxID-related diagnosis code data that she targets for the two years covered by her complaint. For instance, for the 2010 review, Relator fails to "[i]dentify the speaker"—or in this case, the actor—alleged to have submitted data from DxID's review to CMS. *Ladas*, 824 F.3d at 25. Relator describes interactions with her "superiors" without identifying any specific names. FAC ¶¶ 81, 120, 124, 126. While Relator generally alleges that 4,578 diagnosis codes resulted from DxID's review and were submitted to CMS sometime "prior to January 31, 2012," FAC ¶ 112, she offers *no* particularity as to who

submitted the data, when the data was submitted, from what location the data was submitted, or who from GHC instructed or caused DxID to submit such data.

Relator instead makes allegations about what multiple unrelated "Defendants" did without specifying their respective actions. *See, e.g.*, FAC ¶¶ 90–95. Relator thus fails to differentiate GHC from other Defendants as is required to plead with particularity how *GHC* violated the FCA. Even under Rule 8's more lenient pleading standard, the Second Circuit has explained that a complaint must "give each defendant fair notice of what the plaintiff's claim is and the ground upon which it rests." *Atuahene v. City of Hartford*, 10 F. App'x 33, 34 (2d Cir. 2001) (quotation omitted). A complaint "lumping all the defendants together in each claim and providing no factual basis to distinguish their conduct . . . fail[s] to satisfy this minimum standard." *Id*. at 34; *see also Apace Commc'ns v. Burke*, 522 F. Supp. 2d 509, 517–18 (W.D.N.Y. 2007) (finding that "lump[ing] multiple defendants together" likewise does not satisfy Rule 9(b)).

Moreover, as discussed in further detail below, Relator concedes that she actually reviewed less than 5 percent of the codes she challenges, meaning that her FAC does not reach in any meaningful manner nearly 4,400 of the codes it mentions. FAC ¶¶ 121, 125. And of the 200 codes Relator claims to have reviewed, she offers only *four* patient examples that she alleges are miscoded, FAC ¶¶ 142–47, and even these allegations do not withstand scrutiny as discussed *infra* at p. 15.

Thus, Relator pleads only generally that *codes were submitted* to CMS for GHC beneficiaries for 2010 dates of service, some small number of which were not documented in a manner Relator believed necessary, falling far short of the particularity Rule 9(b) demands. This cannot possibly support FCA claims as CMS has long espoused that data "perfection" is not the

standard to which MAOs should be held. *Medicare Program: Medicare+Choice Program*, 65 Fed. Reg. 40,170, 40,268 (June 29, 2000) ("[MAOs] cannot reasonably be expected to know that every piece of data is correct, nor is that the standard that [CMS], the OIG, and DoJ believe is reasonable to enforce.").

Relator's conclusory allegations about DxID's review for 2011 dates of service are even more deficient: she provides *no* examples, as she must. *Chorches*, 865 F.3d at 86; s*ee also United States ex rel. Wood v. Applied Research Assocs.*, 328 F. App'x 744, 750 (2d Cir. 2009). She alleges only that "[u]pon information and belief, DxID's review process for 2011 *likely* generated more unsubstantiated codes than the previous review because DxID had more time to conduct its review." FAC ¶ 138 (emphasis added). Relator provides no basis for this information and belief. *Johnson v. Univ. of Rochester Med. Ctr.*, 686 F. Supp. 2d 259, 266 (W.D.N.Y. 2010) (Larimer, J.) (noting that when alleging based on information and belief, "a plaintiff must still set forth the factual basis for that belief, and that basis must arise from the plaintiff's direct, independent, firsthand knowledge"). A complaint that "merely *speculate[s]* that a claim might exist" fails to meet Rule 9(b)'s strict requirements. *Id.* (emphasis in original); *see also id.* at 267–268.[5]

[5] For 2011, the closest Relator comes to providing anything more than a cursory allegation regarding submission of codes is by alleging that "GHC instructed DxID to submit risk adjustment claims based on a source of documentation previously rejected by GHC and DxID for 2010 dates of service: incidental findings." FAC ¶ 133. But Relator does not allege examples of diagnosis codes from "incidental findings" actually submitted to CMS or why alleged internal GHC or DxID standards from the prior year are an appropriate substitute for CMS requirements for FCA purposes. Further, her description of a prohibition on the submission of "incidental findings" has no merit. CMS has no such restriction; rather, coders are instructed to code the diagnoses documented by the provider. Coders are not to apply clinical judgment to such process. *See* ICD-10-CM Coding Guidelines, § I.A.19 ("The assignment of a diagnosis code is based on the provider's diagnostic statement that the condition exists. The provider's statement that the patient has a particular condition is sufficient. Code assignment is not based on clinical criteria used by the provider to establish the diagnosis."), *available at*

b. Relator has not alleged that any submitted diagnosis codes were false or fraudulent.

Relator's FAC separately fails because it provides no statutory or regulatory authority to support her general allegation that the codes stemming from DxID's reviews were objectively false or fraudulent. *Ladas*, 824 F.3d at 25 (Relator must plead "why the statements [claims] were fraudulent") (quotation omitted). With the exception of some background on the MA program, *e.g.*, FAC ¶¶ 38, 51, 61, 64, Relator's complaint is devoid of any citations to formal MA statutory or regulatory requirements. Instead, Relator's complaint relies on (i) her own subjective views, (ii) vague references to "CMS Rules," and (iii) a single document containing informal sub-regulatory guidance from CMS: a Participant Guide, which CMS describes as a "training . . . to provide participants who are new to risk adjustment the support necessary to understand risk adjustment." *See*, *e.g.*, *Participant Guide*, I-1; FAC ¶¶ 116, 118. Even if this paucity of information could support an FCA claim (and it cannot), Relator does not plead with particularity why diagnosis code data generated by DxID's review did not comply with "CMS Rules" or the Participant Guide. For example, Relator describes Chronic Kidney Disease policies that DxID "encouraged GHC to adopt" and provides a conclusory statement that those policies "violate[] CMS rules for risk adjustment claims," FAC ¶ 101, but cites *nothing* to support that statement. *See* FAC ¶¶ 101–04. In fact, her allegations contradict the plain language of the Participant Guide that she cites. *See supra* Part II.B (alleging, for example, that CMS requires conditions to be treated in order to be coded when the Participant Guide instructs that conditions that "require *or affect* patient care treatment *or* management" should be coded) (emphasis added). Other allegations in her complaint are similarly conclusory and unsupported.

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https://www.csscoperations.com/Internet/Cssc3.Nsf/files/participant-guide-publish_052909.pdf/$File/participant-guide-publish_052909.pdf.

See, *e.g.*, FAC ¶¶ 105–11. While Relator's factual allegations must be taken as true on a motion to dismiss, conclusory statements of the type that riddle Relator's complaint warrant no such deference. *Harris*, 572 F.3d at 72.

Further, Relator's allegations are fundamentally flawed because the vague "CMS Rules" that she mentions and the Participant Guide sections that she references do not relate to items that can be objectively false, but rather to a subjective, interpretive process: diagnosis coding. *See, e.g.*, *United States ex rel. Morton v. A Plus Benefits, Inc.*, 139 F. App'x 980, 982 (10th Cir. 2005) ("At a minimum the FCA requires proof of an objective falsehood . . . . Expressions of opinion . . . or statements about which reasonable minds may differ cannot be false.") (quotation omitted); *see also United States ex rel. Yannacopoulos v. Gen. Dynamics*, 652 F.3d 818, 836 (7th Cir. 2011); *United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376 (4th Cir. 2008). "[I]nnocent mistakes, mere negligent misrepresentations and *differences in interpretations* will not suffice to create liability." *United States v. Corinthian Colls.*, 655 F.3d 984, 996 (9th Cir. 2011) (discussing interpretations in the context of a *regulatory* safe harbor provision) (emphasis added) (quotation omitted). Relator's own analysis of the codes generated by DxID demonstrates the interpretive nature of coding. *See* FAC ¶ 128. For instance, in recounting DxID's re-review of 40 codes Relator submitted for reconsideration, Relator admits (1) that there are *differing reasonable interpretations* of CMS guidance for 25 of the codes and (2) that she *agreed with* 15 of DxID's 40 responses.[6] Relator thus acknowledges *her own review* of these 40 codes had a 37.5% error rate. *See* FAC ¶ 128 (indicating that she reversed her

[6] Relator's "74%" figure does not account for her own agreement with these 15 codes. Even assuming she is correct about the other 133 codes not being supported, she is basing her allegations on less than 2% of the codes allegedly generated from DxID's review, which themselves would be a tiny fraction of the data provided to CMS for GHC members for 2010 dates of service.

original finding for 15 of the 40 records submitted to DxID). Relator's citation to the U.S. Department of Health & Human Services Office of the Inspector General ("OIG") audit of PacifiCare Texas (FAC ¶ 134) further reinforces that differing approaches can be taken to coding, even within government agencies: CMS has acknowledged that its Risk Adjustment Data Validation ("RADV") audit review methodology "differed substantially from the audit methodology used by the HHS Office of Inspector General" in the OIG's audits. U.S. Gov't Accountability Off., GAO-16-76, *Medicare Advantage: Fundamental Improvements Needed in CMS's Effort to Recover Substantial Amounts of Improper Payments* 16, n.38 (2016).[7]

The FAC's four patient examples from DxID's 2010 review further highlight Relator's analytical deficiencies. FAC ¶¶ 140–47. Because Relator does not allege that she reviewed the same records DxID analyzed, it is unclear how her review aligns with DxID's review or with any alleged false diagnoses or claims. Moreover, Relator does not allege that any of the patient examples are tied to specific codes actually submitted to CMS that in turn triggered a risk adjustment payment. And for each of the four patients, Relator's allegations are at best nothing more than non-actionable differences in interpretation. For example, she argues for Patient A that the provider's statement that the patient "does not have *much* in the way of depression" means that the patient did not have depression. FAC ¶ 142 (emphasis added).

In the end, Relator's disagreement with coding standards that do not align with her self-described "conservative" approach to coding, FAC ¶ 81, does not mean that the approach adopted by GHC was incorrect, much less knowingly false or fraudulent, even if more "aggressive" than Relator liked. FAC ¶ 107. Indeed, courts have found that precisely because of relators' subjective experiences, their claims should be subjected to heightened scrutiny:

[7] *Available at* https://www.gao.gov/assets/680/676441.pdf.

> Many potential relators could claim that 'in my experience, this is not the way things are done.' However, relators may not be in a position to see the entire picture or may simply have a subjective disagreement with the other party on the most prudent course of action. Further, their perspective may be colored by considerable bias or self-interest, such as in the case of a disgruntled employee. The heightened possibility of mistake or bias supports the need for a higher standard of specificity for fraud compared to other civil litigation . . . . [Relator's] subjective evaluation, standing alone, is not a sufficient basis for a fraud claim.

United States ex rel. Presser v. Acacia Mental Health Clinic, 836 F.3d 770, 780–81 (7th Cir. 2016); see *id*. (granting motion to dismiss where relator had provided "no medical, technical, or scientific context which would enable a reader of the complaint to understand why [defendant's] alleged actions amount to unnecessary care forbidden by the statute" or "policies or practices at other medical clinics, regulations, or other publications" showing the same).

c. Relator has not alleged that any submitted diagnosis codes were claims for payment that would have resulted in CMS paying GHC funds that it would not otherwise have paid.

Finally, Relator fails to allege with particularity that any inaccurate diagnoses caused CMS to pay GHC more than CMS would otherwise have paid. "The False Claims Act does not create liability merely for health care providers' disregard of Government regulations or improper internal policies unless, as a result of such acts, the provider knowingly asks the Government to pay amounts it does not owe." *United States* ex *rel. Clausen v. Lab. Corp. of Am.*, 290 F.3d 1301, 1311 (11th Cir. 2002); *see also United States ex rel. Platz v. Bank of Am. Corp*., 2016 U.S. Dist. LEXIS 44279, *11 (relying on *Clausen*).

Even if the diagnoses she describes constituted or caused inaccurate claims, Relator does not allege that those diagnoses would have altered the amount paid to GHC by CMS—in other words, that the diagnosis codes were claims for payment. MA members often see their physicians multiple times a year, particularly for management of severe or chronic conditions. A diagnosis code submitted to CMS may be supported by *any* record for the year. *See Medicare*

Program: Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs, 75 Fed. Reg. 19,678 at 19,748 (Apr. 15, 2010). Thus, even if one record does not adequately support a particular diagnosis, another record (or multiple records) for the year may. Because Relator does not allege that the diagnoses she identifies in her complaint are *unique* for each member for the year, Relator cannot establish that their falsity would have had any impact on CMS payments.

Nor is it clear from Relator's allegations whether any of the diagnosis codes she finds problematic are still on file with CMS. Relator herself admits that diagnosis codes were regularly corrected; she even includes an entire exhibit showing data corrections. FAC, Exh. 3. Relator also admits that DxID deleted some diagnoses it had initially added because it "later determined [the diagnoses] to be unsupported through a quality control process." FAC ¶ 122. Relator does not allege how or why these various quality-control processes would not have remedied the allegedly false submissions that she simply assumes went uncorrected. *United States ex rel. Gelbman v. City of N.Y.*, 14-CV-771 (VSB), 2018 WL 4761575, at *7 (S.D.N.Y. Sept. 30, 2018) (granting motion to dismiss with prejudice in part because "the SAC does not allege that the edit code was still on the claim when the claim was paid," or that "the provider did not correct the alleged error before resubmitting the claim, and it does not allege any facts about the conduct that led the edit to occur").

Finally, Relator has not alleged that any purported errors, when evaluated at a contract level, surpass the error rate of diagnosis coding found in the traditional Medicare data that CMS uses to calibrate its HCC model. *UnitedHealthcare Ins., et al. v. Azar II*, 330 F. Supp. 3d 173 (D.D.C. Cir. 2018) (vacating CMS rule requiring health plans to repay CMS for diagnosis code errors because of statutory mandate that CMS maintain actuarial equivalence between payment

models for traditional Medicare and Medicare Advantage, both of which have known errors in diagnosis coding). In *UnitedHealthcare Ins.*, the court ruled that requiring MAOs to report and return inaccurate risk adjustment data would violate the Medicare statute in the absence of an accounting for the effect of traditional Medicare coding errors on MA payments. *Id.* at 186-87. Here, Relator seeks to hold GHC to that very same standard. Relator also ignores that when CMS itself conducts RADV audits of MAOs, CMS requires that MAOs repay funds only if CMS determines that the error rate found during the audit exceeds the error rate of the data underlying the payment model. CMS, *Notice of Final Payment Error Calculation Methodology for Part C Medicare Advantage Risk Adjustment Data Validation Contract-Level Audits*, 4–5 (Feb. 24, 2012).[8] Thus, Relator's allegations do not demonstrate that CMS would have paid a penny more to GHC than it otherwise would have even if Relator's allegations are taken as true.

2. Relator fails to allege that any "false claims" were material to CMS's decision to pay GHC.

Relator also fails to meet the rigorous materiality standard for an FCA claim. *Escobar*, 136 S. Ct. at 2002. Here, Relator fails to plead with particularity that: (1) compliance with the sub-regulatory guidelines Relator cites were material to CMS's decision to pay; and (2) any specific violations of such guidance were tied to GHC's alleged submission of false claims.

a. Relator fails to allege that compliance with the sub-regulatory guidance she cites was material to CMS's decision to pay GHC.

As discussed *supra* at p. 13, Relator's allegations do not rely on any statutory, regulatory or contractual requirements—the potential bases for materiality. Rather, she relies only on vague

[8] *Available at* https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/recovery-audit-program-parts-c-and-d/Other-Content-Types/RADV-Docs/RADV-Methodology.pdf. CMS proposed some changes to the RADV process in 2018 that are still in the rulemaking phase. The process detailed in the 2012 Notice remains operative.

"CMS Rules" and a sub-regulatory Participant Guide.[9] Nowhere has she alleged that compliance with this sub-regulatory guidance is material to CMS's decision to pay, nor can she. *See Escobar*, 136 S. Ct. at 1994 (finding that even "statutory, regulatory, and contractual requirements *are not automatically material*, even if they are labeled conditions of payment") (emphasis added). On analogous facts, a district court granted a defendant's motion to dismiss where the relator had similarly "not pointed to a single instance where CMS sought to deny or recoup funds for any degree of non-compliance with the [relevant] requirement, much less non-compliance with technical sub-regulatory guidance such as that alleged here." *United States v. San Bernardino Mountains Cmty. Hosp. Dist.*, No. EDCV 17-00002 JGB (KKx), 2018 WL 5266867, at *9 (C.D. Cal. Sept. 27, 2018) (addressing compliance with CMS sub-regulatory guidance on payments to facilities in rural or remote locations); *see also United States ex rel. Scharff v. Camelot Counseling*, No. 13-cv-3791 (PKC), 2016 WL 5416494, at *8 (S.D.N.Y. Sept. 28, 2016) (granting motion to dismiss where relator failed to "allege whether the government has refused to reimburse clinics that have engaged in conduct similar to [the defendant's conduct]"); *United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1020 (7th Cir. 1999) ("[T]he FCA is not an appropriate vehicle for policing technical compliance with administrative regulations.").

b. Relator has not sufficiently tied alleged violations of binding requirements with specific alleged false claims.

Even had Relator alleged non-compliance with an actual law or regulation (which the FAC fails to do), "mere non-compliance with a regulation is not enough to give rise to FCA

[9] It is telling that Relator cites *only* the Participant Guide and fails to reference any other type of sub-regulatory guidance, such as the ICD-9 Coding Guidelines or Coding Clinic, on which CMS explicitly relies in the Participant Guide and directs MAOs to consult. A complete overview of such guidance would eviscerate her claim.

liability," *Scharff*, 2016 WL 5416494, at *8, when such non-compliance is untethered to any *specific* false submissions. In *Scharff*, the Southern District of New York dismissed the relator's complaint in part for its failure to establish materiality:

> It does not connect specific conduct by [defendant's] counselors to specific submissions for reimbursement, or explain why the purportedly fraudulent conduct was material to the payment of reimbursements. The Complaint does not cite any express condition for reimbursement applicable to [defendant], nor does it allege whether the government has refused to reimburse clinics that have engaged in conduct similar to [defendant's].

Id.; *see also United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1265 (9th Cir. 1996) (garden-variety regulatory noncompliance is not actionable under the FCA). Similarly, in this case, while Relator provides a general overview of alleged error categories based on her record review, FAC ¶ 121, she fails to tie any specific diagnosis codes actually submitted to CMS to specific material non-compliance with applicable law or regulation. Moreover, even assuming that Relator happened to identify a few diagnoses that were coded erroneously and submitted by mistake, mistakes by themselves are not actionable under the FCA: Relator must plead with particularity that specific non-compliant conduct resulted in specific false submissions to the government. After all, "[g]iven the millions of participants in Medicare, it is only to be expected that some diagnostic codes will be reported in error for a patient who does not have that illness or condition." *UnitedHealthcare Ins., Co. v. Azar II*, 316 F. Supp. 3d 339, 343 (D.D.C. 2018); *see also* Medicare Program: Medicare+Choice Program, 65 Fed. Reg. 40,170, 40,268 (June 29, 2000) ("simple mistakes will not result in sanctions").

3. Relator fails to plead the elements of a conspiracy claim under Section 3729(a)(1)(C) or facts to support such a claim.

Relator fails to plead the basic elements of a conspiracy claim, let alone plead those elements with the requisite particularity. To plead conspiracy under the FCA, a relator must show that "(1) the defendant conspired with one or more persons to get a false or fraudulent

claim allowed or paid by the United States and (2) one or more conspirators performed any act to effect the object of the conspiracy." *United States ex rel. Taylor III v. Gabelli*, 345 F. Supp. 2d 313, 331 (S.D.N.Y. 2004) (quotation omitted). Conspiracy claims must be pleaded with particularity. *See United States v. Strock*, No. 15-CV-0887-FPG, 2018 WL 647471, at *10 (W.D.N.Y. Jan. 31, 2018) (Geraci, J.).

Relator fails to plead even these basic elements. Rather, she baldly asserts a violation of the FCA's conspiracy provision, FAC ¶¶ 151–59, without the elements of a claim for conspiracy or any facts to support one. Her vague and conclusory allegations of conspiracy involving different and unrelated Defendants are insufficient. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, (2007) (holding that even "a formulaic recitation of the elements of a cause of action will not do"). The Second Circuit has affirmed dismissal of a complaint that similarly failed "to identify a specific statement where [defendants] agreed to defraud the government." *Ladas*, 824 F.3d at 27 (quoting the district court).

4. Relator fails to plead the elements of a "reverse false claim" under Section 3729(a)(1)(G) or facts to support such a claim.

A so-called "reverse false claim" under "section 3729(a)(1)(G) requires (1) that the defendant had an obligation to pay money to the government, (2) that the defendant used a false statement to avoid or decrease that obligation, (3) that the false statement was material, and (4) that the defendant made the false statement knowingly." *United States ex rel. Davern v. Hoovestol, Inc.*, No. 11–CV–6630 CJS, 2015 WL 6872427, at *9 (W.D.N.Y. Nov. 9, 2015) (Siragusa, J.) (quotation omitted). Rule 9(b)'s demanding requirements also apply to allegations of reverse false claims. *See, e.g., United States ex rel. Piacentile v. Amgen, Inc.*, 336 F. Supp. 3d 119, 135–36 (E.D.N.Y. 2018). Relator once again does not allege the elements of this claim against GHC, let alone facts to support it. Instead, Relator makes a general allegation that

Defendants "refuse[d] to correct . . . previously submitted risk adjustment claims when defendants discover, or in the exercise of reasonable care should discover, that those previously submitted claims were false." FAC ¶ 7.

B. The FAC Should Be Dismissed Because Relator Has Not Alleged that GHC Acted Knowingly

Under the FCA, the knowledge element can be satisfied by actual knowledge, deliberate ignorance, or reckless disregard, 31 U.S.C. § 3729(b), but not by mere differences in opinion. At most, the FAC alleges that GHC disagreed with Relator about how to apply sub-regulatory CMS guidance. This precludes a knowledge finding because a "reasonable interpretation of any ambiguity inherent in the regulations belies the scienter necessary to establish a claim of fraud under the FCA." *United States ex rel. Ketroser v. Mayo Found.*, 729 F.3d 825, 832 (8th Cir. 2013) (affirming dismissal of relator's alleged violations of "Medicare regulation and CPT codebook"). As described *supra* at p. 14, Relator admits that there are differing reasonable interpretations of CMS guidelines and that she changed her mind about the validity of 37.5% of the codes she discussed with DxID. FAC ¶ 128. Relator cannot plausibly plead knowledge of false submissions when, by her own admission, GHC simply had a difference of opinion about how to apply the applicable sub-regulatory guidance. *See* FAC ¶ 81. Pleadings must include "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Additionally, Relators must "plead the factual basis which gives rise to a strong inference of fraudulent intent." *Tessler*, 712 F. App'x at 29 (quotation omitted); *see also United States ex rel. Colucci v. Beth Israel Med. Ctr.*, 785 F. Supp. 2d 303, 316–17 (S.D.N.Y. 2009) (finding that relator's "inability to identify any regulation violated by defendants demonstrates that defendants' interpretation of the Medicare regulations was not unreasonable, and thus not knowingly false or fraudulent" and that the "alleged facts create only

a 'mere possibility' that defendants acted knowingly and are insufficient to plead the 'knowing' conduct element" of an FCA claim). Because Relator fails to show how GHC's interpretation was *incorrect*—let alone recklessly or deliberately so—Relator has not sufficiently pleaded and cannot establish the necessary scienter.

Relator must also plausibly plead that GHC knew that CMS would have refused to pay because of the coding practices Relator challenges. *Escobar*, 136 S. Ct. at 1996 ("What matters is . . . whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision."); *Strock*, 2018 WL 647471, at *9. In *Strock*, the Court concluded that the plaintiff government agency had "not alleged that it expressly conditioned payment to [defendant] on [defendant's] compliance" with applicable contracting requirements. 2018 WL 647471, at *9. The Court noted that the plaintiff had alleged that the *defendant* had knowledge of defendant's own non-compliance with the contracting requirements, but not that the defendant "had knowledge that *Plaintiff*, as a matter of course, refuses to pay… because of non-compliance with [applicable] contracting requirements." *Strock*, 2018 WL 647471, at *9 (emphasis added). Relator similarly does not establish that GHC had knowledge that CMS would not pay GHC if CMS was aware of the DxID coding standards that Relator has questioned. In any event, the guidance is not clear enough to plausibly establish that GHC adopted a standard that it *knew* to be incorrect.

C. The FAC Should Be Dismissed with Prejudice Because Allowing Relator to Amend Would Be Futile

Although district courts grant leave to amend "when justice so requires," Fed. R. Civ. P. 15(a)(2), leave to amend "should generally be denied in instances of futility, undue delay, bad faith or dilatory motive, repeated failure to cure deficiencies by amendments previously allowed, or undue prejudice to the non-moving party." *Burch v. Pioneer Credit Recovery, Inc.*, 551 F.3d

122, 126 (2d Cir. 2008). An amendment is futile "if the proposed amendment fails to state a legally cognizable claim or fails to raise triable issues of fact." *AEP Energy Servs. Gas Holding Co. v. Bank of Am. N.A.*, 626 F.3d 699, 726 (2d Cir. 2010). Allowing Relator to amend would be futile here—three years since her last complaint, during which time she has had more than ample time to investigate—she *has not* alleged, because she *cannot* allege, the most basic and essential facts supporting a claim. Relator must allege that GHC submitted false claims but her allegations are not supported by any relevant legal requirement. Relator must allege that any false claims were material to CMS's decision to pay, but she offers no allegations that CMS considers compliance with the cited sub-regulatory guidance to be material to payment. Relator must allege that GHC had knowledge of false submissions, but she has alleged only that she and GHC had differing opinions about complex sub-regulatory guidance. Standing alone, any one of these deficiencies would justify dismissal with prejudice. Taken together, they compel it.

V. CONCLUSION

For the foregoing reasons, the FAC should be dismissed with prejudice under Rules 12(b)(6), 9(b), and 8(a).

Dated: October 16, 2019

Respectfully submitted,

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